DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

6378 '04 FEB 13 P1:50

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
5282 Lyngate Court
Burke, VA 22015

FEB 13 2004

Re: Health Claim Petition: Glucosamine and Chondroitin Sulfate, and (1) Osteoarthritis; (2) Osteoarthritis-related joint pain, tenderness, and swelling; (3) Joint degeneration; and (4) Cartilage deterioration

Dear Mr. Emord:

The Food and Drug Administration (FDA) has reconsidered its October 3, 2003, letter denying this health claim petition (petition), which you submitted on behalf of Weider Nutrition International, Inc. and which FDA received on May 29, 2003.

FDA is filing the petition for comprehensive review, as provided for in 21 CFR 101.70(j)(2), and will further consider nine of the twelve claims, including the three claims that clearly concern reducing the risk of a disease or health-related condition:

Glucosamine may reduce the risk of osteoarthritis (OA).
Chondroitin sulfate may reduce the risk of OA.
Glucosamine and chondroitin sulfate may reduce the risk of OA.

FDA also intends to consider the claims set out below, but the agency advises that it has not yet reached a final decision as to whether these claims are claims to reduce the risk of a disease or health-related condition and therefore fall within the framework established by Congress for health claims.

Glucosamine may reduce the risk of joint degeneration.
Chondroitin sulfate may reduce the risk of joint degeneration.
Glucosamine and chondroitin sulfate may reduce the risk of joint degeneration.
Glucosamine may reduce the risk of cartilage deterioration.
Chondroitin sulfate may reduce the risk of cartilage deterioration.
Glucosamine and chondroitin sulfate may reduce the risk of cartilage deterioration.

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FDA continues to believe that the claims set out below are not claims to reduce the risk of a disease or health-related condition, and therefore do not fall within the framework established by Congress for health claims. Accordingly, we do not intend to consider those claims.

Glucosamine may reduce the risk of OA-related joint pain, tenderness and swelling.
Chondroitin sulfate may reduce the risk of OA-related joint pain, tenderness and swelling.
Glucosamine and chondroitin sulfate may reduce the risk of OA-related joint pain, tenderness and swelling.

These claims are not health claims for two reasons. First, each claim relates to characteristic signs or symptoms of the disease of OA, i.e., joint pain, tenderness and swelling. See our October 3, 2003, letter, at 3. Second, the inclusion of the phrase "osteoarthritis-related" further indicates that the claim relates to signs or symptoms of OA in people who already have that disease. Thus, even though each claim uses the phrase "may reduce the risk of," none of the claims makes any sense as a risk reduction claim. The language of the claims indicates that they are aimed at people who have OA and who are experiencing and need relief from its symptoms. A claim to relieve a symptom is a drug claim within the meaning of section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FDCA), because to relieve a symptom is to treat or mitigate a disease, and such a claim does not fall within the scope of the health claims provisions in section 403(r) of the FDCA. See Whitaker v. Thompson, 239 F. Supp. 2d 43 (D.D.C. 2003), aff'd, 353 F.3d 947 (D.C. Cir. 2004).

Please feel free to contact Dr. Kathleen Ellwood, the Director of the Division of Nutrition Programs and Labeling, at 301.436.1450, if you have any questions concerning this letter.

Sincerely yours,

L. Robert Lake
Director
Office of Regulations and Policy
Center for Food Safety and Applied Nutrition